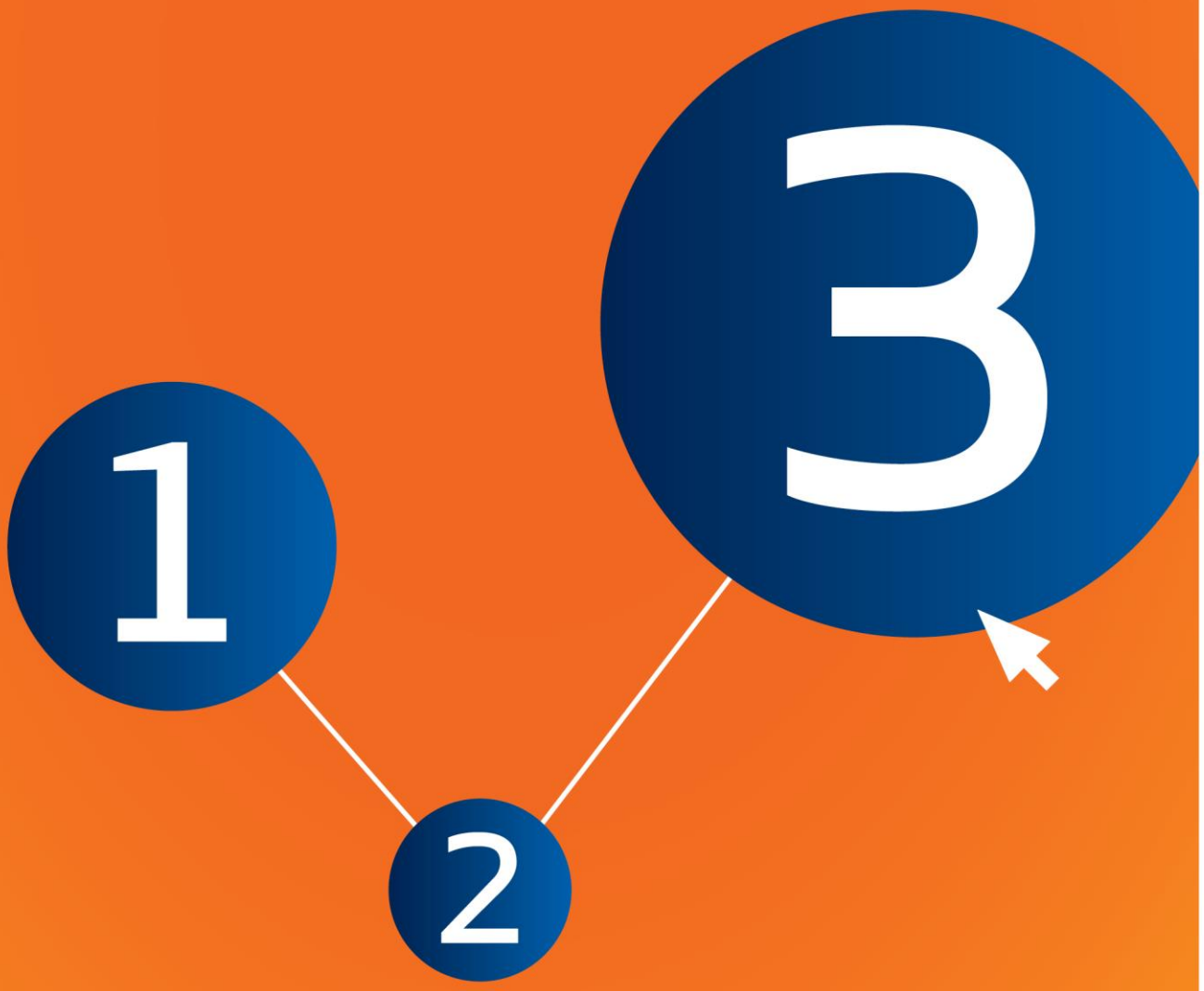
ECHA
EUROPEAN CHEMICALS AGENCY

MANUAL

How to prepare a substance in articles notification



Changes to this document

Version	Changes
2.0	January 2017: Links added to translated versions of this document.
1.0	First version

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1. Introduction

1.1. Objective

The purpose of this manual is to assist forthcoming notifiers in the preparation of a IUCLID Substance in Articles (SiA) notification dossier under the REACH Regulation (EC) No 1907/2006. More precisely it outlines the IUCLID sections and fields to be further filled-in after downloading the substance datasets from the website of the European Chemicals Agency (ECHA), in order to prepare a complete SiA notification dossier according to Article 7 (2) of the REACH Regulation and submit it successfully.

> This manual assumes that IUCLID has been installed and you have a valid ECHA account.
>
> More information about the different functionalities in IUCLID and how to use those functionalities can be found in the help system built-in IUCLID (see chapter 1.5 *Functionalities of IUCLID*).

In order to help as much as possible potential notifiers, pre-filled IUCLID substance datasets are available in the **Candidate List of substances of very high concern for Authorisation** on ECHA website at the following address: http://echa.europa.eu/candidate-list-table.

Those datasets have been pre-filled with basic information on substance identity, composition and classification. ECHA recommends potential notifiers to use them as a starting point. You should check and amend if necessary the information included and complete the rest of the required information following the instructions given in this manual.

In principle, producers and importers of articles are required to prepare a SiA notification when all conditions of Article 7(2) of REACH are met:

- The substance is included in the Candidate List of Substances of Very High Concern (SVHC) for authorisation (hereafter referred to as Candidate List);
- The substance is present in articles produced and/or imported above a concentration of 0.1% w/w;
- The total amount of the substance present in all articles produced and/or imported, which contain more than 0.1% w/w of the substance exceeds 1 tonne per producer and/or importer per year.

A Substance in Articles notification shall be made no later than 6 months after the substance has been included in the Candidate List. This obligation has been applicable since 1 June 2011 for substances included in the Candidate List before 1 December 2010.

Once a notification has been submitted, notifiers are strongly encouraged to keep their notification up-to-date. The notification can be updated in case the notified information changes (see chapter 11. *Update dossier*).

One notification should concern one substance on the Candidate List. If articles you import or produce contain more than one of the substances on the Candidate List, you need to submit a separate notification for each substance. If several articles contain the same substance, you need to include them all in one notification.

> For more information on Substance in Article (SiA) notifications (Article 7(2) of REACH), please consult the dedicated ECHA webpage at http://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles

and the *Guidance on requirements for substances in articles* at:
http://echa.europa.eu/guidance-documents/guidance-on-reach

1.2. Overview of the preparation and the submission of a dossier

A SiA notification IUCLID dossier is a non-editable snapshot file of the substance dataset for the Candidate List substance contained in your article. It contains the information to be submitted to ECHA.

The steps below indicate the approach for the preparation of a IUCLID dossier for your SiA notification, when a pre-filled substance dataset is available on ECHA's website:

Step 1. Sign-up in REACH-IT and create the *Legal entity* for the notifier (https://reach-it.echa.europa.eu/), if necessary.

Step 2. Download the pre-filled substance dataset from ECHA's website (see chapter 5).

Step 3. Import the substance dataset to IUCLID (see chapter 6).

Step 4. Enter further information into the substance dataset in IUCLID (see chapter 7).

Step 5. Create a REACH notification of Substance in Article dossier in IUCLID (see chapter 8).

Step 6. Export the notification dossier from IUCLID (see chapter 9).

Step 7. Submit the notification dossier to ECHA via *REACH-IT* (see chapter 10).

In the rare cases where a substance dataset is not available in the Candidate List website, you can create one by following the Manual *How to prepare registration and PPORD dossiers* available at http://echa.europa.eu/manuals.

1.3. Information requested for a Substance in Article notification

The information to be included in the notification is described in the REACH Regulation (Article 7(4)). The requested information comprises the following (the corresponding IUCLID section is indicated in brackets):

- identity of the notifier (i.e. the producer or importer of articles), i.e. name and contact details (REACH-IT account and IUCLID section 1.1);
- identity of the notifier and role in the supply chain (IUCLID section 1.1);
- identification of the substance, i.e. substance name, EC number, CAS number, type of substance and substance composition (IUCLID sections 1.1 and 1.2): this information is provided in the pre-filled substance dataset;
- the registration number of the Candidate List substance, if available (IUCLID section 1.3);
- classification of the Candidate List substance according to the CLP criteria (IUCLID section 2.1): this information is provided in the pre-filled substance dataset;
- the production site of the notifier, to be filled-in only by producers of articles, not by importers of articles (IUCLID section 3.3);
- a brief description of the use(s) of the substance(s) in the article [technical function(s)] and of the uses of the article(s) (IUCLID section 3.5);
- the tonnage band of the substance contained in the article(s), i.e. 1-10 tonnes, 10-100 tonnes, 100-1000 tonnes or ≥1000 tonnes (IUCLID dossier header).

Chapter 7. *How to complete a dataset in IUCLID* describes in detail how you can complete a Substance in Article notification in order to fulfil your obligations under Article 7(2) of the REACH Regulation.

1.4. Checks performed by ECHA on the submitted dossiers

All dossiers submitted to ECHA undergo initial technical and administrative checks. Such checks are called business rules (BR).

A dossier will be accepted only if all of the relevant business rules, such as format verification and availability of administrative information are satisfied.

For more information on the business rules check refer to the Annex 1: *Overview of the business rules checks performed by ECHA on the submitted dossiers.*

1.4.1. The Validation assistant

The *Validation assistant* (VA) plugin has been developed to enable you to perform some checks on the dossier before you submit it to ECHA via REACH-IT.

Therefore, before the submission, we strongly advise you to use the *Validation assistant* plugin in two steps:

i. To check your dataset (before the dossier is created) to be able to correct any failures reported at this level.

ii. To check the final dossier and address any issues identified in this step.

Using the plugin in both steps is vital for you to minimise any unnecessary failures and potential rejection of your submission.

For instructions on how to run the *Validation assistant*, refer to the help system of IUCLID.

1.5. The functionalities of IUCLID

The functionalities of IUCLID are described in detail in the help that is built in to the IUCLID application. To view the help, press the F1 key anywhere inside the application. The help system will try to display the most relevant part of the help content. From there it is possible to navigate to the specific help required. For example, if the export wizard of the application is open, pressing F1 should open the help content at a description of *the* Export functionality. As an alternative to pressing F1, there are links to help in the application interface, wherever there is a help icon in the form of a question mark.

2. Legal entity

Submissions to ECHA are done by *Legal entities* which have to be defined including contact details prior to submission. The contact details of the company are stored as a *Legal Entity Object (LEO)*. You can create a LEO both in IUCLID and in the *ECHA accounts* available at http://echa.europa.eu/support/helpdesks/echa-helpdesk/echa-accounts.

Note that ECHA will use only the contact details of the legal entity that you have registered in the ECHA accounts or in REACH-IT.

You have already created one legal entity when you installed IUCLID. You can add more legal entities by right clicking on *Legal entity* on the IUCLID home page. However, ECHA will not enforce the consistency between the IUCLID legal entity and the ECHA accounts legal entity.

Please note that by the default settings the legal entity is not included in the dossier. If you wish to include the legal entity in your dossier, you can change the default settings during the dossier creation in the dossier creation wizard (see chapter 8. *How to create a Dossier*).

If you include a legal entity in the dossier which will be submitted to ECHA it may be beneficial to check if the legal entities in IUCLID and REACH-IT are the same. For further information on how to create a Legal Entity Object (LEO) and how to synchronise it between IUCLID and REACH-IT, refer to the Manual *How to create Registration and PPORD dossiers*.

3. Legal entity site

Only producers of articles which produce their articles in the European Union will have to enter their production sites. Article importers do not need to fill in this information. A *Legal entity site* is an entry where you, as a producer of articles can indicate the site where production of your article takes place. This information includes the name of the site, the address and other contact details of the site, and the possibility to include the identifiers of the site under other Company/Organisation IT systems. The *Legal entity site* belongs to only one *Legal entity owner*.

Note that it is not possible to create a site without linking it to a legal entity, but it is possible to modify the link between a site and its legal entity owner by selecting another legal entity from your inventory. More than one legal entity site can be associated with the same legal entity.

3.1. Creating a Legal entity site

Step 1. To create a new site right-click on *Legal entity site* on the home page and select *New*.

Step 2. Provide a name for the site and assign it to the *Legal entity owner* by clicking on the button.

Step 3. Fill as many fields as possible under the *General information and Contact address.* The minimum data required is the *Country* where the site is located.

Step 4. To save the legal entity site information click on from the main menu.

4. Contact

In the *Contacts inventory* you can insert the contact details of the relevant competent persons, such as person responsible for the safety data sheet (SDS), toxicologist, etc, which can be attached to the IUCLID dossier. This person may be contacted to provide assistance or ask about the information submitted.

Information on the contact person responsible for your submission must be specified and managed in REACH-IT.

4.1. Creating a contact

Step 1. To create a *new contact* right-click on the *Contacts* on the home page and select *New.*

Step 2. Complete as many fields as possible under the *General information*.

Step 3. To save the contact information click on from the main menu.

5. Downloading pre-filled substance datasets

A Substance in Article notification dossier is prepared for a substance, as defined under Article 3(1) of the REACH Regulation, which is included in the Candidate List of Substances of Very High Concern for authorisation. The information related to the Candidate List substance you want to notify, such as the identity of the substance and its composition, is already specified in the substance dataset (*Substance dataset*) created for that substance and made available to download on ECHA's website. The dataset is used as basis for creating a IUCLID dossier.

Please proceed as follows to download a pre-filled substance dataset for the Candidate List substance you want to notify:

Step 1. Go to the "Candidate List of Substances of Very High Concern for authorisation" on ECHA's website at http://echa.europa.eu/candidate-list-table

Step 2. Under the column IUCLID dataset, in the correspondent row for the Candidate List substance you want to notify, click in the symbol

Step 3. Download and save the pre-filled *Substance dataset* file to your computer.

After downloading and saving to your computer the dataset of the substance you are going to notify, please proceed to chapter 6. *Importing a substance dataset to IUCLID* for instructions.

The IUCLID pre-filled substance datasets for Candidate List substances, available on ECHA's website, are provided as a support for companies preparing notifications for Substances in Articles. The notifying company remains, however, solely responsible for the appropriateness and correctness of the information submitted in the notification. The pre-filled substance datasets contain the correct substance identifiers in section 1.1 and 1.2, together with relevant classification information in section 2.1. Please note that despite the presence of certain required information in the above mentioned IUCLID sections, you are required to enter further information as described in chapter 7. *How to complete a dataset in IUCLID* of this Manual (e.g. the Legal entity in section 1.1).

A *Substance dataset* is a repository of administrative and scientific data for a substance. In IUCLID, the identification information on a given substance or a given constituent of a substance, such as chemical names (EC name, CAS name, IUPAC name, synonyms, etc.), identity codes (EC number, CAS number), molecular and structural information are stored as a *Reference substance*. The information in the *Substance dataset* can be modified: you can add, remove or change information in the dataset. You can find more detailed information on reference substance and on how to manage a substance dataset in the Manual *How to prepare registration and PPORD dossiers* available at http://echa.europa.eu/manuals.

6. Importing a Substance dataset to IUCLID

To create a Substance in Articles notification dossier in IUCLID, you need first to import to your local IUCLID installation the previously downloaded Substance dataset (see chapter 5).

The steps below show how to import the downloaded pre-filled Substance dataset for the Candidate List substance you want to notify to IUCLID:

Step 1. On the IUCLID home page, click on the *Import* , which will launch the *Import assistant*.

Step 2. On the Import assistant window, click on *Add files* button. A new window will open.

Step 3. Select the substance dataset file (.i5z/.i6z) from the folder where you have saved it during the download process in your hard drive. Then, click on the *Open* button.

Step 4. Press the *Finish* button in the Import assistant window.

Step 5. When the import is complete a popup notification appears on the bottom right-hand corner of the IUCLID screen. You can click on this or the flashing red circle to show the *Background job console*.

Step 6. Once your substance dataset is imported, you can retrive it from the *Substance inventory* by clicking on the Substance on the IUCLID home page.

Step 7. All available substances are displayed in the navigation panel on the left part of the screen. To open your dataset by double-click or right-click on it panel select *Open*.

For more information on Import function refer to the help system of IUCLID.

After importing the pre-filled Substance dataset to IUCLID, you are now ready to complete it with further information as explained in the next chapter, in order to prepare your SiA notification IUCLID dossier.

7. How to complete a dataset in IUCLID

This chapter outlines which information you must provide through the different sections of the IUCLID to prepare a Substance in Articles notification dossier.

When entering your data you can use the help system of IUCLID which is built inside the application. To view the help, press the F1 key anywhere inside the application and the most relevant information will be displayed in the help window.

Once you have downloaded and imported a pre-filled Substance dataset for your substance, you can modify the information in the dataset: you can add, remove or change information in the dataset. The dataset will be used to create the SiA notification IUCLID dossier.

The steps below show how you can complete the pre-filled Substance dataset for your substance:

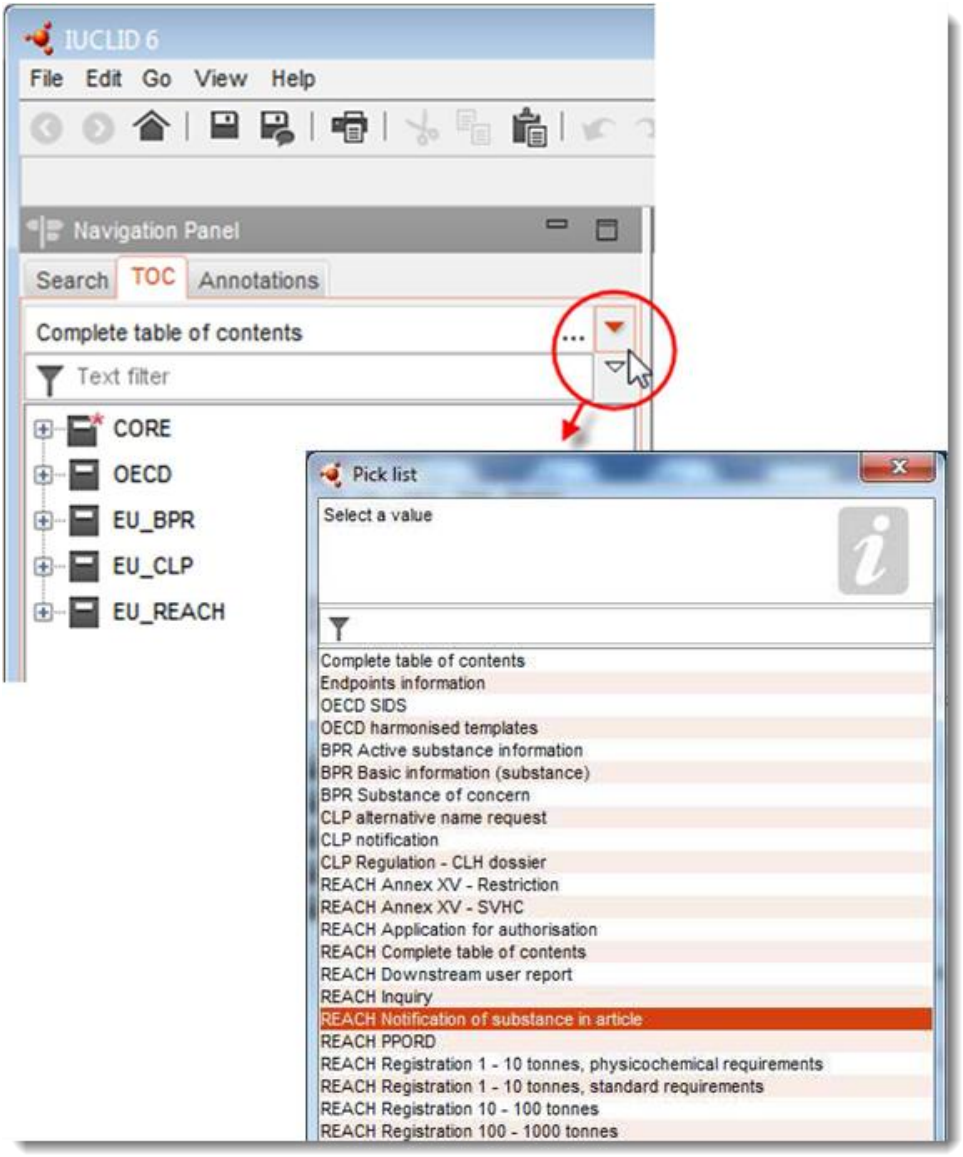
Step 1. Retrieve the Substance dataset you have already imported to IUCLID (see chapter 6), by clicking on the *Substance button* on the IUCLID home page under Main tasks. The Substance dataset is displayed in the navigation panel on the left part of the screen (under *Search* tab).

Step 2. Open the Substance dataset by double-clicking on it or right-clicking and select *Open*;

Step 3. After opening the Substance dataset, to view the Table of contents (TOC) that is relevant for the SiA notification dossier, click on the *TOC* tab in the navigation panel and then on the filled downward button ( ) in the right side of the TOC tab;

Step 4. Select the *REACH Notification of substance in article* option from the picklist of different submission types and then click the *OK* button;

Figure 1: Selecting the REACH Notification of substance in article template from the picklist



Step 5. The sections relevant for a SiA notification dossier are now displayed in the navigation panel on the left part of the screen. Sections including mandatory information to complete are marked with the asterisk ( );

Step 6. Complete the Substance dataset by checking and entering the required information for a SiA notification in this dataset, into each section of IUCLID, as described in

detail in the next sections of this chapter. The sections are shown with their name and the numbering used in IUCLID.

When filling in the different parts of a dataset it is important, that:

- when you create many rows in a table, you must fill in the relevant information in each row,
- when *other* is selected in a picklist the adjacent text field marked with 'Other' must be completed,

when a field is associated with a unit, this must be filled in.

7.1. Section 1 General information

In section 1, *General information*, of IUCLID specify the information on substance identification and the identity of the notifier, as required under Article 7(4) of the REACH Regulation, as explained below.

7.1.1. Section 1.1 Identification

Section 1.1 contains information on the identity of the notifier, the role in the supply chain, identification of the substance, and the type of (reference) substance.

To complete this section, follow the steps:

Step 1. In the *Substance name* field, type the name of the Candidate List substance for which you are preparing the SiA notification dossier.

Step 2. If you have any confidentiality concerns about the substance name, you need to fill in the *Public name* field. In this field you have to indicate a generic name suitable for publication, which appropriately describes the substance.

More information on how to derive a *public name* for a substance for use under the REACH Regulation, you can find at http://echa.europa.eu/manuals.

Step 3. Assign a *Legal entity* to your substance dataset by clicking on the button (see chapter 2. *Legal entity*).

You can NOT appoint a *Third party representative* for a notification of substances in articles.

Role in the supply chain:

Step 4. Select the checkbox *Manufacturer* (for producer of articles), *Importer* (of articles) or *Only representative* in this section according to your role in the supply chain. If you are both a producer and an importer of articles containing the same Candidate List substance then tick both boxes: *Manufacturer* and *Importer*.

Identification of substance and Type of substance:

Information on substance identification is pre-filled in the *Substance dataset* that you downloaded. The information given is sufficient to identify the substance and there is no

need to provide any further information. If you agree with the pre-filled information we recommend you to skip this section.

The following information is pre-filled:

- The field *Reference substance* is filled with the name of the reference substance and the EC Number/EC name and/or CAS number/CAS name and/or the IUPAC name.
- The field *Type of substance* is filled in (mono-constituent, multi-constituent or UVCB).

In addition to these minimum requirements, you have the possibility to also provide all the information specified in section 2.1 to 2.3.4 of Annex VI to the REACH Regulation as mentioned in REACH Article 7(4)c. For that, please refer to the Manual *How to prepare registration and PPORD dossiers*.

An update of a notification successfully submitted (i.e. the notification has received a reference number) must always specify an EC number in the *Reference substance* section of IUCLID section 1.1. Please use the EC number or provisional EC number granted to your previous successful notification submission for this substance.

Contact person:

Step 5. You can add information of the contact person(s) for that specific substance in the *Contact persons* field from the previously defined contacts (see chapter 4. *Contact*).

To enter your data click on the ⊕ button.

Step 6. Click on the chain button to assign a contact from your inventory.

Step 7. To save the information click from the main menu.

7.1.2. Section 1.2 Composition

Section 1.2 of IUCLID is used for describing the identity of the substance at a compositional level. This section should indicate the identity, degree of purity and concentration of the constituents in the substance, including any impurities and additives. The state and form of the substance must also be specified in this section.

Information on substance composition is pre-filled in the Substance dataset that you downloaded. The information given on substance composition is sufficient and there is no need to provide any further information. If you agree with the pre-filled information, we recommend you to skip this section. However, if you have more detailed information that you would like to provide, then please follow the instructions below.

The following information is usually pre-filled:

- The fields *Name*, *Type of composition* and *State/form* contain the information regarding the name and type of the composition, as well as the physical state or form.
- The field *Degree of purity* is filled by default as ≤ 100 %.
- For mono-constituent substances the field *Constituents* contains the information filled under *Reference substance* in section 1.1 Identification.
- The field *Typical concentration* field is pre-filled by default as ≤ 100%.
- For multi-constituent substances the field *Constituents* contains the identification information of the various constituents.

- The field *Concentration range* is filled by default as > 10% and < 80 %.

Use this section to specify some of the information requested under Article 7(4) of the REACH Regulation, on the identity of the substance to be notified at a compositional level that you may have available.

Each substance dataset must contain at least one composition which refers to the substance to be notified. Each composition is a new record in IUCLID. To create a new record and fill in the information on your substance composition, please refer to the Manual *How to prepare registration and PPORD dossiers*.

7.1.3. Section 1.3 Identifiers

In this section you can insert identifiers for regulatory programmes. In particular, this section should be used to report the following identifiers when available: REACH registration number and REACH substance in article notification number (in case of notification update, see below).

To enter your data, you must first create a new record by right-clicking on the section name and selecting a *new fixed record*.

Step 1. Press *Add* button to add a new identifier to the *Regulatory programme identifiers* table.

Step 2. Depending on the type of submission, select the appropriate identifier from the *Regulatory programme* picklist.

Step 3. Enter the relevant number in the *ID* field, the REACH registration number has the following format: 01-XXXXXXXXXX-CC-XXXX.

Step 4. Click on *OK* and the added regulatory programme identifiers will appear in the table.

Step 5. If you need to provide more than one programme identifier, create a new row by repeating the previous steps.

Step 6. To save the information click from the main menu.

Importers of articles may not have access to a registration number of the substances in the article. Producers of articles, incorporating the Candidate List substance into the article themselves, should normally have access to the registration number via the Safety Data Sheet (SDS) of the substance. However, in that case the article producer should verify that his use is covered by the registration, in which case he is exempted from the notification obligation.

For notification updates:

In this section you should add the reference number (notification number) that has been already granted to your substance, in case you want to submit a Substance in Articles notification update, by following the steps above, taking into account the following:

- From the *Regulatory programme* picklist, select *REACH substance in article notification number*;
- Please note that a notification number has the following format: 03-XXXXXXXXXX-CC-XXXX.

7.2. Section 2 C&L and PBT assessment

There are two sections in IUCLID for entering information relating to classification and labelling (C&L), 2.1 GHS and section 2.2 DSD - DPD. In addition, the section 2.3 PBT assessment allows to store the outcome of the PBT assessment performed under the REACH Regulation.

The subchapter below contains relevant information for your SiA notification on the section 2.1 GHS of IUCLID. For more information on this section and its subsections in IUCLID, please refer to the Manual *How to prepare registration and PPORD dossiers.*

7.2.1. Section 2.1 GHS

The Classification and Labelling information is in the pre-filled Substance datasets available for download from web-page of the Candidate List. Therefore, that information is pre-filled in the Substance dataset that you downloaded. It contains sufficient information on classification and labelling. However, if you would like to provide more detailed information or a Substance dataset is not available for the substance you want to notify, then please follow the instructions below.

Supporting information for each substance can be found on the Candidate List of substances of very high concern for Authorisation on ECHA's webpage by clicking the Details button in the specific substance row of the web-page of the Candidate List:
http://echa.europa.eu/candidate-list-table

The classification and labelling information in the pre-filled Substance datasets was taken from the Annex VI to the CLP Regulation, where available:
http://echa.europa.eu/regulations/clp/legislation

Information on how to fill in Section 2.1 of IUCLID can be found in the Manual *How to prepare registration and PPORD dossiers.*

7.3. Section 3 Manufacture use and exposure

7.3.1. Section 3.2 Estimated quantities

In this section you have the possibility to provide information on the tonnage of the Candidate List substance present in the article.

To insert information on the tonnage, please proceed through the following steps:

Step 1. Create a new record by right-clicking on the section name (3.2 Estimated quantities) and selecting a *New record*.

Step 2. Fill in the *Year* field with the calendar year for which the tonnage calculation has been made.

Step 3. Under *Tonnages relevant for registration/notification of substances in articles*, please provide information on tonnage (tonnes/year) that is relevant to your articles:

- tonnage of the Candidate List substance contained in the imported articles in the field *Tonnage imported in articles*

  and/or

- tonnage of the Candidate List substance contained in the produced articles in the field *Tonnage in produced articles*.

You can calculate and provide (for both cases mentioned above) the total tonnage of the Candidate List contained in the articles. The *Guidance on requirements for Substances in Articles* available at http://echa.europa.eu/guidance-documents/guidance-on-reach gives you some advice on how to carry out the calculations.

Step 4. To save the information click button from the main menu.

For articles which have been produced/imported for at least three consecutive years, the tonnage to be reported should correspond to the average tonnage produced/imported during these three full years (or average of two full years if the article has been produced/imported for two full years). Otherwise the tonnage will be calculated based on the previous calendar year only and no averaging will be made.

In case production/import of the article starts in the current year and it is expected that the article producer/importer will fall under the notification obligation (the 1 tonne threshold has been or will be exceeded) you are advised to notify as soon as the 1 tonne threshold has been reached. In that case, please indicate an expected tonnage for the whole year.

You have the possibility to indicate the tonnage that you have provided in this section as confidential. In that case a justification has to be provided, please proceed as follows:

Step 1. To add confidentiality to the flag of this section, on the top of the section, click on the no flag is set button.

Step 2. On the set flags window under confidentiality, click on the downward button ▼ to open the picklist. On the list, select one of the reasons for confidentiality: *CBI*, *IP* or *No PA*.

Step 3. Enter the required justification it into the field *Justification*, which is a free text field. After confidentiality is set, the flag icon in this section will appear as confidentiality flag ( ).

Step 4. To save the information click button from the main menu.

For more information on indicating information as confidential, please refer to manual on confidentiality requests and dissemination available at http://echa.europa.eu/manuals.

7.3.2. Section 3.3 Sites

Only producers of articles will have to enter their articles production sites. Importers of articles do not need to fill in this information.

To enter your data create a new record by right-clicking on the section name (3.3 Sites) and selecting a *New record*. To include a production site in this record, first create a site using the same *Legal entity* that you used for the creation of the dataset (see chapter 3 *Legal entity sites*). To specify the information on your articles production sites, you can create several records (one for each site) and each of them must have one of the existing *Legal entity sites* linked to it by the chain button . When reporting the production site, the country is expected to be the same as the country of the submitting *Legal entity.*

7.3.3. Section 3.5 Use and exposure information

The section 3.5 is composed of a number of sub-sections corresponding to the different life cycles stages of a substance. In the context of a notification for substance in articles, only the subsection 3.5.6 *Service life* must be completed. In this sub-section you have to describe the article(s) and its use(s).

It is recommended to follow the principles explained in the *Guidance on information requirements and chemical safety assessment,* Chapter R.12: *Use description* (available at http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment).

7.3.3.1. Section 3.5.6 Service life

The steps described below show how the different fields should be filled in. Detailed information on the expected content of each field can be accessed clicking the help button.

Step 1. Right-click on *Service life* and select *New record*. A service life record is then created. When creating a new record you can re-name it by pressing F2 button and inserting, as needed (cf. examples below) the name assigned to each article or each use of the article you wish to describe.

You can create several service life records if needed.

In general it is advised to describe separately (i.e. in different *Service life* records) the different articles containing the same Candidate List substance. Similar articles should however be grouped together and the information provided only in one record. To this aim you should decide which articles are similar enough to be described together. This can be done based, namely, on all the following conditions:

- the articles have the same use/function; and
- the Candidate List substance has the same technical function; and
- the Candidate List substance is located in the same (integral) part/material of the article; and
- the use conditions of the articles can be expected to be similar.

Example 1: The Candidate List substance is contained in the single seat and back rest piece of chairs. The seat and back rest piece is an article made of a plastic material. This article exists in different designs, sizes and colours. These variants should however all be considered as the same 'type of article'. Articles that only differ in design, size or colour, can be grouped together in the same *Service life* record.

Example 2: The Candidate List substance is used as waterproofing agent in textile fabrics made of polyester fibres. In one case the substance is used in very low concentration in the fabrics for everyday clothing, where frequent skin contact and regular cleaning with releases to the environment, e.g. during washings, are expected . In the other case the substance is used in high concentration for fabrics used to produce boat sails, where limited skin contact and no frequent cleaning are expected. However, during use there are releases to the environment. These articles should not be grouped in the same *Service life* record, because their uses/functions and use conditions are different which means that not all conditions above are met.

The following (types of) articles, where relevant, should be described in separate *Service life* records:

- articles only used by workers;
- articles with high potential release of the Candidate List substance during use.

Step 2. Under *Registration/Notification status for the use*, click on the dropdown button (▼) and choose from the picklist: *use of substance in articles notified according to REACH Article 7(2)*. Then, click *OK*. This selection will narrow down the list of fields to be filled in. Indeed, not all fields initially displayed when creating a record under *Service life* are relevant for substance in articles notification.

Step 3. Provide a *Service life number* for the service life record, if deemed useful for your own purpose.

Step 4. Provide the service life name (or name/use of your article). Insert, in the *Service life name* field, a short name. The name should be concise but descriptive of the specific article you are describing and of its use, e.g. insulation element, computer cables etc.

Step 5. Provide further description of the article and of its use(s). In the field *Further description of use*, provide more information on the article and its use(s).

Please fill in this section, for example, by including the information below:

- description of the article and its different (integral) parts/materials, when applicable;
- information in which part(s)/materials the Candidate List substance is present and its maximum concentration (w/w); precise technical function of the Candidate List substance in the article or part(s)/materials of the article;
- description of all the different foreseen 'uses' during the service life (e.g. processing into finished article (for semi-finished articles), installation, maintenance and use of the finished article, disposal). Highlight to the extent possible where releases can be expected;
- Indicate if the article is intended to be used by vulnerable populations (e.g. babies, children, pregnant women);
- In the case you are grouping similar articles, we advise you to describe the different characteristics of those articles.

Example 3: Single seat and back rest plastic piece of a chair

The article is a single seat and back rest piece of a chair made of polypropylene (PP). It contains 3% w/w of a Candidate List substance used as a flame retardant. The chair, and therefore its seat and back rest piece, is mainly for indoor use, but there may be some outdoor use. When sitting on the chair, this plastic article will come into contact with skin or clothing.

If the article is exposed to heat or a flame, the PP used can burn and melt and generates a highly exothermic combustion reaction. The Candidate List substance is added to PP, in order to disrupt its combustion.

Example 4: Sewer pipe

The article is a sewer pipe made of Polyvinyl chloride (PVC). The PVC sewer pipe contains 1% w/w of a Candidate List substance, which was used as heat stabiliser in the production of the pipe. The pipe will be handled and mounted by workers. It is foreseen for outdoor use. The pipe comes into contact with the soil and with sewage water from homes/buildings and industrial sites and therefore the Candidate List substance can be released to the environment.

The Candidate List substance is used to prevent thermal degradation of PVC during manufacture and when processed.

Example 5: Semi-finished textile fabric

The article is a semi-finished textile fabric made of polyester fibres. It contains 3% w/w of a Candidate List substance, used as flame retardant. The fabric will be further processed in finishing activities, including washing processes and/or curing processes under elevated temperature. Releases to the environment from these processes are expected, as well as inhalation of vapours and particles by workers.

The finished fabric is used for the production of clothes and home textile articles. Further releases to the environment are expected during washings of these final articles. Contact with skin while wearing the clothing article can be expected. Inhalation of released particles or vapours during use of the final article, in particular from home textiles with large surface areas.

Example 6: Insulated electric wires in a TV

The articles are insulated electric wires contained in an imported TV. The insulated electric wires were made by insulating the copper wire, through extrusion, using a PVC liquid mixture containing 10% w/w of the Candidate List substance. The Candidate List substance is used as plasticiser and its maximum concentration in the insulated wires is 4% w/w.

The insulated wires containing the Candidate List substance in the TV were grouped together because they are similar, even if having different diameters, code colours, and being bundled in cables.

When disposed, the TV should be treated as electronic waste, which includes the insulated electric wires in it.

Step 6. Where several compositions of the Candidate list substance are reported in the section 1.2 (see subchapter 7.1.2), you can link the compositions that are related to this particular use in the table *Related composition* by clicking on *Add* and selecting the relevant composition(s).

Step 7. Indicate by whom the article is foreseen to be used. In the field *Article used by*, please indicate if the article is foreseen to be used by *workers*, or by *consumers* (i.e. by the general public) by clicking on dropdown button (▼). You should not select both *workers* and *consumers* within one service life record.

Article foreseen to be used by consumers (e.g. screw, hammer) can also be used by workers. It is enough to report these articles as article used by consumers if the use conditions are generally the same.

Step 8. In the field *Article category (AC)*, you should select the type of article(s) into which the Candidate List substance has been incorporated from a list of standard articles categories (e.g. wood articles, plastic articles). In case of an article with various (integral) parts/materials (e.g. painted paper clip), please choose the article category describing the part of the article where the Candidate List substance is present. Select the article category (AC) from the pick list, by clicking on dropdown button (▼).

The Article Categories (AC) are listed in the Table R.12-14 in the Appendix R.12.4. of the *Guidance on information requirements and chemical safety assessment*, Chapter R.12: *Use*

description. The Table also includes explanations and examples, as well as suitable TARIC chapters, for some AC.

If you cannot identify a suitable article category (or you wish to be more specific), please select *AC0: Other* and provide explanation in the adjacent field. If applicable, you can select a code (and the corresponding phrasing) from the TARIC system (http://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp)

In principle, articles that are assembled or joined together remain articles, therefore, articles categories AC1 to AC3 are recommended to be used in combination with the relevant material-based article categories AC4 to AC13 or AC0.

Step 9. Describe the use of the articles from the perspective of release to the environment.

i. Create one *Contributing activity / technique for the environment*, by clicking the ⊕ button.

ii. Under the field *Name of activity / technique* briefly characterise with your own words the use of the articles from an environmental perspective.

iii. Under *Environmental release category (ERC)*, select from the standardised list of environmental release categories (ERCs) the one(s) that best describe the use of the articles, by clicking on dropdown button (▼). It is possible to choose several ERCs, if appropriate.

You will find the list of ERCs together with explanation and examples in the Tables R.12-12 and R.12-13 of the *Guidance on information requirements and chemical safety assessment, Chapter R.12: Use description* (see Appendix R.12.4.). Please also refer to the figure R.12.7 in this appendix for a decision tree for the ERC assignment.

If the articles described within a use have different conditions of uses from an environmental perspective, this can be indicated by creating several *contributing activities/techniques for the environment*. Additional contributing activities can be created by clicking on the ⊕ button.

Step 10. Describe the use of the articles from the human health exposure perspective.

- If you have indicated that your **article is used by consumers** in the field *Article used by*, you will have the possibility to create *Contributing activity / technique for consumers*;

- If you have indicated that your **article is used by workers** in the field Article used by, you will have the possibility to create Contributing activity / technique for workers.

Contributing activities/techniques are created by clicking the ⊕ button.

i. Under the field *Name of activity / technique* briefly characterise with your own words the specific use of the article from an human health exposure perspective.

ii. If you have selected *consumers* under *article used by*: under *Article category (AC)*, select from the standardised list of articles categories in the picklist menu the one(s) that best characterise the article from an exposure perspective (e.g. AC6a –leather articles, large surface area articles) by clicking on dropdown button (▼). If you cannot identify a suitable article category please select *AC0: Other* and provide explanation in the adjacent field.

iii. If you have selected *workers* under *article used by*: under *Process categories (PROC)*, select from the standardised list of process categories available in the picklist menu the appropriate one(s) by clicking on dropdown button (▼),

e.g.*PROC 21:Low energy manipulation of substances bound in materials and/or articles*.

iv. If none of the specific PROC categories seems applicable, you can tick the box *PROC0: Other* and describe in the adjacent field, the foreseen tasks, application techniques or process types in your own words.

A process category for articles used by workers describes the tasks, application techniques or process types defined from the occupational perspective. You can find the name, explanation and examples of these PROCs in Table R.12-11 in the Appendix R.12.4. to the *Guidance on information requirements and chemical safety assessment,* Chapter R.12: *Use description*.

v. In the field *Percentage (w/w) of substance in mixture / article (%)*, please provide the concentration (% w/w) of the Candidate List substance present in the article as imported or produced. In the field *Details on the percentage of substance in a mixture / article*, you can provide more detailed information on the concentration reported. The obligation to notify applies when this concentration is above 0.1 % (w/w). This concentration threshold applies to each article of an imported object made up of more than one article, which were joined or assembled together.

If the articles described within a use have different conditions of uses from a human health exposure perspective, this can be indicated by creating several contributing activities / techniques. Additional contributing activities can be created by clicking on the ⊕ button.

Step 11. Provide a description of the use(s) – as technical function - of the Candidate List substance in your article.

Under *Technical function of the substance during use* select the appropriate technical function of the substance in the article from the picklist, by clicking on dropdown button (▼). If the substance remains in the article from a preceding life cycle stage, and does not have any function in the article, you can select from the picklist *no technical function*. Further explanation can be provided in the field *Further description of use* (see step 5).

The technical function (TF) of the substance in the article describes the role that the substance fulfils when it is used (what it actually does in an article). The technical function is therefore focused on substances, and it is not meant to convey information on the type of article.

The list of specific TFs are listed in Table R.12-15 in the Appendix R.12.4. to the *Guidance on information requirements and chemical safety assessment,* Chapter R.12*: Use description*. If none of the listed technical functions (TF) seems applicable, you may describe it in your own words, instead of assigning a specific available TF. In that case you should tick the box *Other* and provide the relevant description in the adjacent field.

Step 12. In the field *Tonnage of substance for this use (tonnes/year)*, please report the tonnage (tonnes/year) of the Candidate List substance contained in the article you are describing, e.g. 1.5 (tonnes/year in the sewer pipe). As a minimum requirement, the tonnage range of the Candidate List substance has to be provided in the IUCLID dossier header (Chapter 8). In the next field, you have the possibility to provide more detailed information on the tonnage if you so wish.

Step 13. The field *Details on tonnage reported* can be filled with more detailed information on the tonnage reported in the field above, if necessary, e.g. how the tonnage value has been calculated. Note that the checkbox *Total EU tonnages for this use* is not relevant for the SiA notification and should NOT be selected.

Step 14. In the *Remarks* field you can provide additional information you consider relevant for the Substance in Article notification dossier, in particular further information related

to exposure resulting from the use of the article (considering the service life of the article including disposal), e.g. results from a chemical safety assessment of article service life. You may also consider to include information for safe and proper use/handling of the article, as well as appropriate instructions for its disposal that you communicate down the supply chain in accordance to Article 33 of REACH Regulation.

Step 15. To save the information click button from the main menu.

If you need to notify more than one type of article or use containing the same Candidate List substance, you need to create several records under the *Service life* following steps 1 to 15 above.

You have the possibility to indicate the information on use that you have provided in this section as confidential. In that case, proceed as follows:

Step 1. To add confidentiality to the flag of this section, on the top of the section, click on the no flag is set button.

Step 2. On the set flags window under *confidentiality*, click on the downward button ▼ to open the picklist. On the list, select one of the reasons for confidentiality: *CBI*, *IP* or *No PA*.

Step 3. Enter the required justification it into the field *Justification*, which is a free text field. After confidentiality is set, the flag icon in this section will appear as confidentiality flag ( ).

Step 4. To save the information click button from the main menu.

8. How to create a Dossier

Once you have included all relevant information in your substance dataset, the next step is to create a dossier.

Before creating a dossier you are advised to check the completeness of your substance dataset by running the *Validation assistant*. For more information on how to run the Validation assistant refer to the help system of IUCLID.

This may also be a good time to verify if the quality of the dataset can be improved before creating a dossier, please check the webpage *How to improve your dossier* on the ECHA website: http://echa.europa.eu/support/how-to-improve-your-dossier

Step 1. To create a dossier open the list of available substance datasets by clicking on the *Substance* on the IUCLID home page.

Step 2. All available substances (within the limits of the search results managed in the user's preferences) are displayed in the navigation panel on the left part of the screen. If a substance does not appear in the list you can search for it using the search panel. If the list is very long, you can also filter by typing (part of) the name of the substance in the filter field.

Step 3. Select the substance for which you want to create a dossier.

Step 4. Right-click on the substance in the query results list. From the pop-up menu select *Create dossier.*

Step 5. After selecting the *Create dossier* option the dossier creation wizard is displayed. Follow the steps in the dossier creation wizard.

Only two steps are displayed in the dossier creation wizard as the default option: *Select submission type* (1) and *Complete the dossier header* (5). If you wish to change the default settings to have more options you can select the checkbox *Use advanced settings*.

Step 1. **Select the submission type**. Choosing the correct dossier template by selecting the submission type is essential for a successful submission. Before exporting your dossier you have to make sure that the selected template corresponds with the intended submission.
When the checkbox Use advanced settings is selected follow the steps 2-4, if the default settings are kept (recommended approach), go to step 5 directly.

Step 2. Define the confidentiality level by selecting the data protection flags. If you have included any confidentiality or regulatory programme flags in your substance dataset, please make sure that the relevant information is included in your dossier by selecting the appropriate flags in this step. If you are unsure it is recommended to select the defaults option 'all fields - including confidential test material'. ECHA will assess the confidentiality of the information and the justifications provided. You can find more information on the publication of part of the dossier on the ECHA website at http://echa.europa.eu/manuals.

Step 3. Select whether the annotations should be included in the dossier.

Step 4. Verify and select which documents and entities will be included in your dossier. To this end, select in the Entities list the substance entity which will be preceded by . The documents and entities connected to the substance will be listed in the References to window; documents to be included are already checked. Certain documents, such as section 1.1, will always be included in a dossier, and cannot be excluded in this step. Likewise, depending on the submission type, some documents will not appear in the list and cannot be included as they are not relevant for the selected submission type. If you are unsure of the information to be included, you can select Next and rely on the default settings for that submission type.

Step 5. **Complete the dossier header** by entering additional administrative information.

Information contained in the dossier header is crucial for business rules checking when you submit your dossier. Missing or incorrect information can result in that your submission cannot be accepted for further processing and will be automatically removed from the system. In this case you need to create a new dossier with corrected information and submit it again. For more information refer to the Annex: *Overview of the business rules checks performed by ECHA on the submitted dossiers*.

The following subchapters describe how to fill in the administrative information in the dossier header.

Note that In the particular case of SiA notification, you should select **REACH Notification of substance in article** template in the *Dossier creation wizard*.

8.1. Administrative information

Enter a *Dossier name*, which enables you to easily identify it in your database. You are advised not to use confidential information in the dossier name, as it will be seen by anyone you share the dossier with.

When relevant, enter a *Dossier submission remark*. This remark can include further information on the reason for the submission (e.g. detail which information has been updated).

8.1.1. Specific submissions

By default the dossier is created for an initial submission, in case of an update you should select the checkbox *The submission is un update*.

For your spontaneous update, you must select the checkboxes *The submission is an update* and *Spontaneous update*. Additionally, select an appropriate *Justification* from the picklist, which is reporting the update reasons for a SiA notification.

If the reason for the spontaneous update is not listed in the picklist, then you are required select *other* and indicate the information about the reason in the corresponding field.

If you need to indicate more than one reason for updating the dossier, you should create an additional repeatable block for each reason by clicking on the button. Please note that a *Justification* has to be provided in all the blocks.

See also chapter 11. *Update Dossier*.

8.1.2. Dossier specific information

This part of the dossier header allows giving more general information on the IUCLID SiA notification dossier submitted.

In the field *Tonnage band* you must select your own tonnage band (i.e. 1-10 tonnes, 10-100 tonnes, 100-1000 tonnes or ≥1000 tonnes).

Confidentiality claim on tonnage band and its *Justification* fields must to be filled in case you want to claim the relevant data confidential. For tonnage band, this is the only way to request the confidentiality.

The checkbox for the *Confidentiality claim on the tonnage band* is the only location in the dossier where you can request confidentiality on your tonnage band. The confidentiality flag in IUCLID section 3.2 relates to the actual tonnage manufactured/imported, which is always treated as confidential information

The checkbox *Reviewed by an assessor* is not required, but if it has been reviewed by an assessor it may be indicated here.

9. How to export a Dossier

To start the export process, first search for the *Dossier* in the navigation panel of the IUCLID application. When the Dossier is shown in the list of search results, right-click on its entry, and then select *Export* from the menu.

For details on the export wizard, see the help that is built in to the IUCLID application.

10. Submit Dossier

To submit your dossier to ECHA you must sign-up in REACH-IT with the legal entity details of the submitting entity, and follow the instructions provided there for your specific type of submission.

You can access REACH-IT from ECHA website: http://www.echa.europa.eu/ or go directly to the REACH-IT website: https://reach-it.echa.europa.eu/.

11. Update Dossier

If you need to update your dossier, you do not need to re-type again all your substance data. Instead you can update the information in the substance dataset. To edit the substance dataset, select it from the navigation panel and fill in or update the relevant data. When the dataset is ready you can create a dossier (see chapter *How to create a Dossier*).

It is strongly recommended to keep the SiA notification up to date. You should consider updating your notification if the information you have included in it changes. Reasons for updating could be a change in the tonnage range, in the characteristics of the article produced/imported (description, use(s)) etc. In all these circumstances, updating your notification is strongly recommended. Keeping your notification up to date will help document your REACH compliance towards national enforcement authorities.

Do not forget to specify in section 1.3 of IUCLID the reference number (notification number) that has been already granted to your substance, in case you want to submit a notification for Substance in Articles update (see chapter 7.1.3. *Identifiers*).

Annex 1. Overview of the business rules checks performed by ECHA on the submitted dossiers

Business rules are a set of dossier format and administrative pre-requisites that must be fulfilled before ECHA can establish that the dossier can be handled properly. Business rules do not assess the completeness or compliance of the data provided. If the dossier submission fails at the business rule level, the dossier will be automatically removed from the system, and a new submission is required. You can see the outcome of the business rules check in the submission report in REACH-IT.

This document will guide you through the basic requirements of creating the substance dataset and the IUCLID dossier header. In addition, it is recommended to use the IUCLID Validation Assistant plugin on the substance dataset and also on the final dossier before exporting it from IUCLID and submitting it to REACH-IT. Right-click on your substance dataset or on the dossier in the IUCLID navigation panel and select *Validate*. This plugin will check most of the business rules. However, some of the business rules depend on the information that is stored within the REACH-IT database, and therefore the plugin cannot simulate all the business rules checked by the Agency.

Business Rules applicable for Substance in Article notifications		
Location (IUCLID/REACH-IT)	**Rule description**	**Relevance**
IUCLID **substance dataset**	A REACH dossier must be created from a substance dataset. It cannot be created out of a mixture or product dataset.	All dossier types
IUCLID **substance dataset**	When creating a dossier where a category will be included, the dossier has to be created out of a substance dataset that is linked to a category.	Substance in Articles notification
IUCLID **section 1.1 – Identification**	A reference substance must exist in section 1.1	All dossier types
IUCLID **section 1.1 – Identification;** **section 1.2 – Composition**	Each reference substance in section 1.1 and 1.2 must contain a substance identifier. An acceptable substance identifier is: - EC/List number - CAS number - IUPAC name Any EC/List number defined in section 1.1 and 1.2 of IUCLID must exist in the REACH-IT EC inventory. If you use a reference substance to report unknown constituents/impurities, they must be “identified” by inserting “Unknown constituent/impurity” in the IUPAC name field. If categories are used, this rule is applied to all the	All dossier types

	category member substances.	
IUCLID **section 1.1 – Identification**	At least one of the following fieldsmust be provided for the reference substance in section 1.1: - EC/List number - CAS number - Molecular formula AND molecular weight AND structural formula - SMILES notation - Remarks	Substance in Articles notification
IUCLID **section 1.1 – Identification**	In an update submission, the substance must be identified by an EC/List number.	Substance in Articles notification
IUCLID **section 1.1 – Identification**	The reference substance must be marked as one of the following: - Mono constituent substance - Multi constituent substance - UVCB	Substance in Articles notification
IUCLID **section 1.1 – Identification;** **section 3.3 - Sites**	When 'Manufacturer' is selected as a role in the supply chain then at least one manufacturing site must be provided in section 3.3. To this end, you must create a record in section 3.3 and assign a 'Site' to this record. In addition you must assign at least one manufacture use from section 3.5.1 using the field 'Related manufacture/own use'.	Substance in Articles notification
IUCLID **section 1.1 – Identification**	The 'Only representative' as a role in the supply chain cannot be marked together with 'Manufacturer' or 'Importer'. Separate legal entities and registrations/notifications are required for each non-EU manufacturer represented.	Substance in Articles notification
IUCLID **section 1.2 – Composition**	At least one composition must be defined in section 1.2. The following requirements are also to be fulfilled: - All created compositions must contain at least one constituent. - All constituents must be linked to a reference substance.	All dossier types
IUCLID **section 1.2 – Composition**	All compositions created in section 1.2 must have the composition type indicated. At least one of the compositions in section 1.2 must reflect the composition of the substance manufactured/imported by the registrant. This composition must be marked as the "Legal entity composition of the substance". If the composition type "other" is selected from the list, the relevant information must be provided in the adjacent free text field.	All dossier types
IUCLID **section 1.1 – Identification;** **section 1.2 – Composition**	If the substance is defined as mono-constituent, the first 'legal entity composition of the substance' in section 1.2 has to have a matching substance identity when compared	All dossier types

	with the reference substance in section 1.1.	
IUCLID **section 1.1 - Identification;** **section 1.2 – Composition**	If the substance is defined as a multi-constituent substance, the reference substance in section 1.1 cannot be identical to any of the constituents defined in the first composition of type 'legal entity composition of the substance' in section 1.2.	All dossier types
IUCLID **section 1.2 – Composition**	All constituents of a multi-constituent or of a UVCB substance must identify distinct reference substances.	All dossier types
IUCLID **section 1.2 - Composition**	If the substance is classified, a 'Hazard category' and a 'Hazard statement' must be provided, or a 'Reason for no classification' for each hazard class in IUCLID section 2.1 should be indicated. If the substance is not classified, the tick box 'Not classified' should be marked and no classification should be provided in that record.	Substance in Articles notification
IUCLID **section 1.2 - Composition**	If the substance is classified, at least one block for 'Specific target organ toxicity - single' and 'Specific target organ toxicity - repeated' must be provided in IUCLID section 2.1. For each block, a 'Hazard category', a 'Hazard statement', and 'Affected organs' must be provided, or indicate a 'Reason for no classification'. If the substance is not classified, the tick box 'Not classified' should be marked and no classification.	Substance in Articles notification
IUCLID **section 1.3 - Identifiers**	When a registration number is provided in section 1.3 it has to refer to the same substance as indicated in section 1.1.	Substance in Articles notification
IUCLID **section 1.3 – Identifiers**	For an update submission, a reference number must be given in IUCLID section 1.3.	Substance in Articles notification
IUCLID **section 2.1 - GHS**	The classification and labelling information must be provided in the GHS format in section 2.1 - GHS.	Substance in Articles notification
IUCLID **section 2.1 - GHS**	If at least one classification is provided in a C&L record in section 2.1 then: - a 'Signal word' must be provided in the 'Labelling' block of the same record. - a 'Hazard statement' or a 'CLP supplemental hazard statement' must be provided in the 'Additional labelling requirements' block of the same record. If no classification is provided, the tick box 'Not classified' should be selected and no hazard statements and no signal words should be provided.	Substance in Articles notification
IUCLID	For each 'Specific concentration limit' block that is created	Substance in Articles

section 2.1 - GHS	in a C&L record in IUCLID section 2.1, at least one of the two fields under 'Concentration range (%)' must be provided. In addition, at least one selection must be made under 'Hazard categories'. If no classification is given in a C&L record, the tick box 'Not classified' should be marked and no specific concentration limits should be indicated in that record.	notification
IUCLID **section 3.3 - Sites**	Assign a site to each record in IUCLID section 3.3. You must also provide a contact address for the site; 'Country' is the minimum information required.	Substance in Articles notification
IUCLID **section 3.5.6 – Service life**	At least one record in section 3.5.6 has to be included, containing the following information: - 'Service life name' - 'Article used by' - 'Further description of use' - at least one 'Contributing activity / technique for the environment' described with the appropriate 'Environmental release category (ERC)' codes - 'Technical function of the substance during use' In addition: - if the article is used by workers, the appropriate 'Article category (AC)' codes must be provided. - if the article is used by consumers, at least one 'Contributing activity / technique for consumers' must be provided described with the appropriate 'Article category (AC)' codes. -If 'other:' is selected in any of the picklists then the adjacent free text field must be filled in.	Substance in Articles notification
IUCLID **dossier header**	Once a reference number for a registration/notification is granted, it is not allowed to submit another initial submission for the same substance from the same legal entity. If you need to modify/add data, an update submission is required.	Substance in Articles notification
IUCLID **dossier header**	Updates can be submitted in the following cases: - Following the successful registration / notification of this particular substance, after having received a reference number (spontaneous update). - Following a technical completeness check (TCC) failure (requested update). - Following a request for further information by the Agency (spontaneous or requested update as specified in the request). In any other case, an initial submission is required.	All dossier types - Updates
IUCLID **dossier header**	If you wish to submit a spontaneous update then the following conditions must be fulfilled:	Substance in Articles notification

	- In the dossier header tick the boxes 'The submission is an update' and 'Spontaneous update'. - Insert the submission number to the last successful submission as the 'Last submission number'. - Select an appropriate justification for updating by first creating a block under 'Spontaneous update' and then making a selection in the pick-list. If you selected 'other:', you are required to give the reason in the adjacent free text field.	
IUCLID dossier header	Legal entity change cannot be performed by submitting and update to the dossier. The 'Legal entity change' module in REACH-IT is to be used to carry out the administrative changes related to ownership of the registration/notification.	Substance in Articles notification
IUCLID dossier template	The dossier template used in IUCLID must correspond with the intended submission type in REACH-IT.	All dossier types
REACH-IT	A new dossier cannot be submitted when the previous submission for the same substance is still being processed.	All dossier types - Updates
REACH-IT	No submissions can be made from the account of a legal entity, which at the time of submission undergoes the legal entity change (merge) process. Legal entity change functionality is available in REACH-IT.	All dossier types
REACH-IT	Parallel submissions are not allowed for the same annotation number. You cannot submit a dossier quoting the same annotation number while another dossier is still being processed.	Substance in Articles notification
REACH-IT	It is not allowed to submit a notification when when a registration dossier for the same substance from the same submitting legal entity is currently under processing by the system.	Substance in Articles notification
REACH-IT	If an active registration already exists for the substance by the submitting legal entity then it is not allowed to submit a notification.	Substance in Articles notification
REACH-IT	The same IUCLID dossier cannot be submitted more than once.	Substance in Articles notification
REACH-IT	It is not allowed to update a dossier that is being deactivated or has been revoked.	Substance in Articles notification

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